Hospital pharmacy isolators: the future

From large-scale centralised services and facilities serving a number of hospitals to small-scale units, the development of isolators is keeping pace with the requirements of regulation, health and safety and new standards

ENVAIR
Integrity in clean air

John Neiger

Consultant

Envair Limited
Haslingden
UK

W:www.envair.co.uk

Isolators have now been in use in UK and certain European hospital pharmacies for over 15 years. When isolators first appeared on the scene in the late 1980s, they originated from three distinct sources, reflected in the respective design solutions. The first source related to the nuclear industry and utilised components from that industry to develop large "sterile" isolators. These had very low air change rates and were gassed with peracetic acid. Materials were transferred between "sterilising" isolators, storage isolators and process isolators using sophisticated docking containers. The second source related to a well-known manufacturer of radiopharmaceutical products. Here the focus was on radiation protection and the technology relied on negative pressure and a turbulent airflow. The third source related to a collaboration of the author's clean air and containment company with two UK hospital pharmacies. The resulting isolators utilised the principles of unidirectional flow to ensure an aseptic environment, with negative pressure where operator protection was required. Transfer chambers, purged with HEPA (high-efficiency particulate air) filtered air, eliminated the transfer of airborne contamination during material transfers in and out.

Developments

Gaseous sanitisation in rapid gassing ports

Hydrogen peroxide is less corrosive than peracetic acid and breaks down into water vapour and oxygen, which are harmless. It has therefore superseded peracetic acid as the gaseous sanitisation agent of choice, especially in regulated facilities. More recently, smaller, slightly less expensive hydrogen peroxide generators with capacities more suited to pharmaceutical isolators than to rooms have reached the market. But the most exciting current development is the rapid gassing port, which replaces the isolator entry transfer device. With a total gassing cycle time of 15–20min, the process of gaseous sanitisation, with all its advantages, has thus been greatly streamlined. This should make it far more attractive in a hospital pharmacy environment, where a speedy turnaround of prescriptions is the normal requirement.

PLC systems

Simple PLCs (programmable logic controllers) are now replacing the old control and instrumentation technology. However, they offer many advantages. A good example is the simplification of pressure decay testing. Previously there was an SOP (standard operating procedure), which the technician had to follow step by step. Depending on the isolator, the PLC can either carry out the whole process automatically from start to finish and then report and log the result, or it can be programmed to give operator prompts for any manual operations. In both cases, there is no need for a detailed SOP, and the scope for operator error is removed. A further advantage of PLCs on isolators is that they can be linked with PLCs on associated equipment, such as hydrogen peroxide gas generators, to provide overall process control and comprehensive interlocking for safe independent use of chambers.

New standards and guidelines

This year has seen the publication of a book on pharmaceutical isolators[1] and of the final draft of *ISO 14644-7*.[2] The former gives guidance on almost every aspect of isolator design and use, whereas the latter sets out basic and generic requirements for the specification and testing of isolators. Together, they should ensure that, as isolators continue to develop, they do so as a result of a deeper understanding by all involved – suppliers, users, testers and, most importantly, regulators. ■

References

1. Midcalf B, Phillips M, Neiger J, Coles T, editors. Pharmaceutical isolators: a guide to their application, design and control. London: Pharmaceutical Press; 2004.

2. *ISO/FDIS 14644-7*: Cleanrooms and associated controlled environments – Part 7: Separative devices (clean air hoods, glove boxes, isolators and minienvironments).